Northern, Eastern and Western Devon Clinical Commissioning Group
South Devon and Torbay Clinical Commissioning Group

Clinical Policy Committee (CPC)
Minutes

Wednesday 31 July 2013, 10.00 am -12.00 pm

Henlake Suite, The Watermark, Ivybridge

Present:

Dr Jo Roberts* (Chair)	GP Clinical Commissioner	South Devon & Torbay CCG
Dr Mick Braddick*	GP Clinical Commissioner	NEW Devon CCG
Dr Andrew Craig*	GP Clinical Commissioner	NEW Devon CCG
Richard Croker*	Head of Medicines Optimisation	NEW Devon CCG
Dr Tawfique Daneshmend	Consultant Gastroenterologist & Hepatologist	RD&E NHS FT
Tracey Foss	Principal Pharmacist	RD&E NHS FT
Dr Keith Gillespie*	GP Clinical Commissioner	NEW Devon CCG
Dr Andrew Gunatilleke	Consultant in Pain Management & Anaesthesia	SDHC NHS Foundation Trust
Andrew Kingsley	Patient Safety and Quality	NEW Devon CCG
Mac Merrett	Lay Member	
Chris Roome	Head of Clinical Effectiveness	NEW Devon CCG
Dr Alison Round*	GP Clinical Commissioner	NEW Devon CCG
Tracey Polak	Assistant Director/Consultant of Public Health	Devon County Council
Alison Wilkinson	Head of Contracting and Business Intelligence	NEW Devon CCG

Guests:

Gareth Franklin	Clinical Guidance Manager	NEW Devon CCG
Catherine Lissett	Consultant in Diabetes and Endocrinology	SDHC NHS FT
Hilary Pearce	Clinical Effectiveness Pharmacist	NEW Devon CCG
Petrina Trueman	Joint Formularies Pharmacist	NEW Devon CCG
Sanjay Verma	Clinical Evidence Pharmacist	NEW Devon CCG

In attendance:

Fiona Dyroff	Clinical Effectiveness Governance Support Officer	NEW Devon CCG
Rebecca Heayn	Clinical Effectiveness Governance Manager	NEW Devon CCG

* Denotes voting members or representative acting for voting member

1. Welcome and introductions

Attendees were welcomed to the meeting and the group introduced themselves.
Dr Darunee Whiting had delegated voting authority to Richard Croker for this meeting
Dr Alison Round, GP Clinical Commissioner, joined the meeting by teleconference.
Dr Catherine Lissett, Consultant in Diabetes and Endocrinology joined the meeting by teleconference for item 9 – Lixisenatide for the treatment of type 2 diabetes.

2. Apologies

Paul Foster	Secondary Care Chief Pharmacist	SDHC NHS Foundation Trust
Dr Stephen Hunt	GP Clinical Commissioner	NEW Devon CCG
Dr Philip Melluish	GP Clinical Commissioner	South Devon and Torbay CCG
Dr Darunee Whiting	GP Clinical Commissioner	NEW Devon CCG

3 Confirmation of voting members and declaration of interests

The six voting members present were noted.

The Clinical Effectiveness Team is investigating the declaration of interest processes used by other organisations. An options appraisal will be brought to the committee at a future meeting.

ACTION: Options appraisal to be brought to a future CPC meeting.

Declarations of interest forms were collected. The chair informed the committee that declarations of interest had been made by a GP Clinical Commissioner and a specialist in diabetes and endocrinology. These would be detailed in the minutes.

No person was excluded from the meeting.

Details of Declaration of Interest are detailed below.

DRUG/TECHNOLOGY TO BE CONSIDERED	PHARMACEUTICAL COMPANY / MANUFACTURER / SERVICE PROVIDER
Lixisenatide (Lyxumia®) **Exenatide** (Byetta®, Bydureon®) **Liraglutide** (Victoza®)	**Sanofi** **Lilly** **Novo Nordisk**
Flutiform® Other inhaled products for asthma	**Napp Pharmaceuticals** **Allen & Handburys/GlaxoSmithKline, AstraZeneca, Chiesi, Meda Pharmaceuticals, Schering Plough, Takeda, Teva, UCB Pharma**
Renavit® **Ketovite®**	**Stanningley Pharma** **Essential Pharmaceuticals**

NAME OF ATTENDEE	ROLE	
Andrew Craig	GP Clinical Commissioner	Received gifts, benefits or sponsorship of any kind, whether refused or accepted worth over £25 or several small gifts worth a total of over £100 from the above or closely related pharmaceutical/manufacturing company/companies. West Hoe Surgery has received sponsorship from Napp and Nova-Nordisk for quarterly clinical governance afternoons. This takes the form of sandwiches at lunch and CPR and fire training annually.
Catherine Lissett	Consultant in Diabetes & Endocrinology	In receipt of payment/gift for transport and hospitality to attend national or international meetings or symposia. In 2007 Nova-Nordisk provided funding for me to attend the annual meeting of the European Association for the Study of Diabetes (EASD).

4. Minutes of the meeting held on 11th June 2013 and matters/actions arising

The minutes of the meeting held on 11 June 2013 were approved.

Actions from previous meeting:

13/03 Policy for dermatological treatments for focal hyperhidrosis to be taken to contracting meeting and issues resolved with PHT

Action complete

13/10 Policy variations to be resolved over the next twelve to eighteen months. Contact local authority Overview and Scrutiny Committee (OSC) lead to appraise them of this plan

At the first meeting of CPC it had been suggested that presenting the plan to harmonise policy variations to a local Authority OSC would be a good idea. Work was well underway and wider discussions suggested that the balance of public interest would be best served by progressing as rapidly as possible. It was noted that clinical specialists in all areas of Devon were consulted during the process for each policy and that the CPC membership has a broad range of skill, knowledge and perspective to assess the suitability of the proposed changes, which tended to be minor in implication. Undertaking analysis and preparing submissions for 3 different local authorities was felt to be unnecessary and disproportionate. Documents are published and decisions can be defended.

Action complete

13/11 Letter to be written to CCG governing bodies regarding alignment of access policies and request that the governing bodies inform the CPC if the proposal is not acceptable.

Action complete

13/14 Aclidinium commissioning policy to be published

Action complete

13/15 FIGS to be made aware of issues around devices affecting generic competition for respiratory products

Action complete

13/16 Glycopyrronium commissioning policy to be published

Action complete

13/17 Indacaterol commissioning policy to be published

Action complete

13/18 GP Clinical Commissioners interested in supporting the NPAG process to contact Chris Roome

Dr Alison Round and Dr Mick Braddick will be involved in supporting NPAG.

Action complete

13/19 Decision making process to be developed for CPC and will be brought back to a future meeting for the group

Action included on the meeting agenda.

5. Decision making discussion

A complete cycle of the CPC and Formulary Interface Groups (FIG) process has now taken place.

The committee considered a number of issues pertinent to commissioning policy including:

- the CCGs' resources are finite and fully allocated. Funding new treatments, which are often more expensive than existing treatment, has a financial impact during the year in which funding is agreed and savings will be needed elsewhere;
- at the time of the decision the needs and potential benefits of the patient group under consideration are in full focus but the potential service losers consequent on a decision to commit extra resources are not apparent;
- assessment of value includes factors of price, outcomes, the level of uncertainty and what we can already achieve within existing resources;
- commissioning policy decisions determine whether routine funding is available. Non routine cases can be funded through individual routes if the exceptional case is supported, in the case of primary care drugs this could be the individual GP deciding to issue a prescription to an individual patient. Even where the CCGs determine that funding will be available local clinicians, through FIGs, can set the place in therapy;
- can potential savings from switching patients from one drug to a cheaper option be realised? Drug prices change and costs can increase when supporting patients who are switched from

one drug to another or if more adverse events occur. Generally clinicians and patients do not like switching;
- the possibility of pharmacies and dispensing GP practices reducing their expenditure on treatments by using cheaper options;
- the safety of using a limited range of drugs with which clinicians are very familiar compared to a wider range.

6. Laser surgery for short sight

Hilary Pearce – Clinical Effectiveness Pharmacist – NEW Devon CCG joined the meeting for this item. The committee were asked to note that as part of the work programme to harmonise policies with variation in access criteria for treatment, the commissioning positions of the three former PCTs for laser surgery for short sight were reviewed. This treatment is covered by the low priority treatment policy for NHS Plymouth and the joint policy on low priority treatment for NHS Devon/Torbay Care Trust. The three former PCTs had the same commissioning position; not to routinely commission laser surgery for short sight. The treatment is not covered by the ophthalmology services commissioned by NHS England. There are no apparent financial considerations for the CCGs.

No further action is required.

7. Circumcision

Hilary Pearce – Clinical Effectiveness Pharmacist – NEW Devon CCG joined the meeting for this item. Policies on circumcision were approved by the NHS Devon Eastern Locality Clinical Leads in July 2012, the NHS Plymouth Professional Executive Committee in October 2010 and Torbay Care Trust Healthcare Funding Request Group in August 2011. These polices are very similar with no clinical differences in criteria for access to treatment. All commission circumcision for: phimosis and paraphimosis, balanitis xerotica obliterans and balanoposthitis. This is in line with and supported by guidance from a number of professional organisations.

The NHS Devon, NHS Plymouth and Torbay Care Trust policies on circumcision will be reissued as a joint NEW Devon CCG and South Devon and Torbay CCG commissioning policy. No changes have been made to criteria for access to treatment or circumstances under which the procedure may be considered on the basis of exceptionality. No financial impact is expected for the CCGs.

ACTION: NHS Devon, NHS Plymouth and Torbay Care Trust policies to be reissued as joint NEW Devon CCG and South Devon and Torbay CCG commissioning policy

8. Planned Treatment Abroad

Hilary Pearce – Clinical Effectiveness Pharmacist – NEW Devon CCG joined the meeting for this item. NHS Devon, NHS Plymouth and Torbay Care Trust had policies on NHS funding of planned treatment abroad. NHS Devon's policy was approved by the PCT's Finance and Contract Committee in September 2010. NHS Plymouth's policy was approved by their Clinical Effectiveness Commissioning Group in March 2011. Torbay Care Trust Healthcare Funding Request Panel approved a policy in August 2011. These policies stated the overarching principles which apply to NHS funding of planned treatment in another European Economic Area (EEA) country. The circumstances under which funding for planned treatment abroad is considered retrospectively are also stated.

NHS guidance on seeking funding for planned treatment abroad has changed. NHS England is now the responsible commissioner and there are no apparent financial considerations for the CCGs.

NHS Devon, NHS Plymouth and Torbay Care Trust policies are no longer valid. The NHS Devon and NHS Plymouth polices will be removed from the NEW Devon CCG Website. The website will indicate that funding of treatment undertaken abroad is the responsibility of NHS England and a link to NHS Choices will be provided for guidance on funding of treatment. South Devon and Torbay CCG will be informed that their policy on planned treatment aboard is not longer valid.

ACTION: NHS Devon and NHS Plymouth policies on Planned Treatment Abroad to be removed from NEW Devon CCG website. Website to indicate that funding of planned treatment aboard is the responsibility of NHS England and a link to NHS Choices to be provided.

ACTION: South Devon and Torbay CCG to be informed that their policy is no longer valid.

9. Lixisenatide for the treatment of type 2 diabetes

The committee were asked to consider evidence for commissioning lixisenatide for the treatment of type 2 diabetes. Petrina Trueman - Joint Formularies Pharmacist – NEW Devon CCG presented an evidence review. Dr Catherine Lissett, Consultant in Diabetes and Endocrinology joined the meeting by teleconference for this item. An application supporting the commissioning of lixisenatide has been received from a consultant at Derriford Hospital on the grounds of being a once daily medication, cheaper than other agents used with basal insulin and having a better side effects profile. The application does not support switching existing stable patients from other agents. An evidence assessment had been carried out by the Clinical Effectiveness Team, NEW Devon CCG.

Lixisenatide (Lyxumia®▼) is a new glucagon-like peptide-1 (GLP-1) agonist indicated for treating adults with type 2 diabetes mellitus in combination with oral hypoglycaemic agents and/or basal insulin when these, together with diet and exercise, fail to provide adequate glycaemic control. This is a once daily drug given via a 60-dose prefilled pen, by subcutaneous injection. It is the third agent in the class of GLP-1 agonists. Current formulary choices throughout Devon include exenatide twice daily, exenatide once daily (as per NICE TA248) and liraglutide once daily (as per NICE TA203). Continuation criteria in NICE guidance for GLP-1 agonists requires a 1% reduction in HbA1c and a weight loss of at least 3% at 6 months.

The committee reviewed the clinical evidence for lixisenatide. Placebo controlled studies have demonstrated that lixisenatide is an effective agent for glycaemic control in type 2 diabetes and is associated with weight loss of around 1kg. Data from comparative studies suggests similar efficacy to existing drugs in measures of glucose control although the comparison study with the most widely prescribed agent in local practice has significant limitations. A consistent picture of a lower degree of weight loss compared to existing GLP-1 agonists is apparent in these studies. Phase 3 placebo-controlled studies showed that there were mean decreases in blood pressure values over time compared to baseline values in both treatment groups during the entire treatment period. The long-term efficacy of lixisenatide over at least 76 weeks was evaluated in 5 studies.

The committee discussed a range of issues pertinent to this therapy:

- A Comparative study has found non inferiority to exenatide for glucose control.
- Cost savings could be made if lixisenatide was used over established drugs, however these may not be realised as NICE TAs mandate the inclusion of liraglutide and exenatide once weekly in local formularies and local clinical opinion does not advocate switching stable patients to lixisenatide. It was also noted that the cost of needles, although expected to be small had not been included in the costings.
- Safety - use of GLP-1 analogues has been associated with pancreatitis. The European Medicines agency and FDA are undertaking a review into pancreatic changes which will report at the end of 2014. It was also noted that clinical trials have shown that patients receiving lixisenatide experience less weight loss than those taking other agents, there is no long term

data on this. Southern Devon and Torbay CCG are cautious at including lixisenatide on its formulary.
- Whether there were meaningful and predictable differences in tolerability. It was noted that a decision not to routinely commission lixisenatide would not mean that it could not be tried in an individual patient who was found to be intolerant of exenatide and liraglutide.
- Other agents are available as a result of NICE guidance, some members felt that there could be a place for lixisenatide and that Formulary Interface Groups should make local decisions.

The committee voted 5 to 1 against commissioning lixisenatide for the treatment of type 2 diabetes.

ACTION: Commissioning policy to be published.

10 Flutiform for asthma in adults and children over 12

An application had been received in support of including Flutiform® in local formularies as an additional but not first line treatment for asthma in adults and children over 12. The application does not support switching existing patients to Flutiform®. An evidence assessment had been carried out by the Clinical Effectiveness Team, NEW Devon CCG. Petrina Truman. Joint Formularies Pharmacist presented the paper.

The committee were asked to review the evidence for commissioning Flutiform for asthma in adults and children over 12. Flutiform® is an inhaled corticosteroid (ICS) and long acting β2 agonist (LABA) combination product containing fluticasone propionate and formoterol fumarate in a pressurised metered dose inhaler (MDI). Flutiform® would provide an additional combination ICS/LABA option of formoterol in a MDI formulation rather than dry powder inhaler. Flutiform®, provides an MDI with a higher licensed dose than Fostair® MDI (which also contains formoterol) and is less expensive than some formulations of Seretide®. Current combination inhaled corticosteroid/ long-acting β-agonists (ICS/LABAs) available are salmeterol/fluticasone (Seretide®) available as dry powder and metered dose inhalers, formoterol/budesonide (Symbicort®) dry powder inhaler and formoterol/beclometasone (Fostair®) metered dose inhaler. Flutiform is not licensed for use in COPD and unlike Symbicort® and Fostair®, neither Flutiform® nor Seretide® are licensed for the relief of asthma symptoms as a maintenance therapy.

The committee reviewed the evidence for Flutiform®. Two comparative studies involving Seretide® and Symbicort®, and five studies comparing Flutiform® to placebo and individual component agents given alone and concurrently had been undertaken. These studies found that Flutiform® is more effective than placebo, fluticasone alone and formorterol alone with respect to changes in FEV1 between baseline and 12 weeks, and discontinuations due to lack of efficacy. Comparative studies have demonstrated non-inferiority to Symbicort® and Seretide® with respect to change in FEV1 at 12 weeks from baseline and discontinuations due to lack of efficacy. A longer term (up to 12 months), open label study assessed the safety of Flutiform® 125/5 mcg and 50/5 mcg. The incidence of adverse events was 36.9% overall.

NEW Devon and South Devon & Torbay CCGs spent just under £12m on combination ICS products in the 12 months to May 2013. It is estimated that if 10% of inhalers currently prescribed as Seretide® or Symbicort® were switched to the equivalent strength of Flutiform®, there could be a cost reduction of £90,000. Currently, Seretide® 50 and 125 Evohalers and Seretide® 100 Accuhaler are similar in cost and Seretide 250 Evohaler is more expensive compared to Flutiform®. Seretide® 500 Accuhaler is cheaper than Flutiform®. However, differences in licensed indications and minimum indicated age may limit the potential. Local specialist opinion does not advocate switching patients who are well controlled on current therapy. The data above will include patients prescribed for COPD, for which Flutiform® is not licensed.

The committee discussed a range of issues pertinent to this therapy.

- It is unlikely that significant potential costs savings will be realised.

- Is there a need for an additional drug? Increasing the range of drugs makes things more complicated, however there could be a niche for the drug with patients who need higher doses. Other options are limited and expensive.
- Use of Flutiform® is more restricted than Fostair®, Seretide® and Symbicort®

The committee voted 5 to 1 against commissioning Flutiform® for asthma in adults and children over 12.

ACTION: Commissioning policy to be published

11 Renavit for the dietary management of water soluble vitamin deficiency in renal failure patients receiving dialysis

An application has been received supporting the prescribing of Renavit® to patients receiving haemodialysis. The committee were asked to consider evidence for this product. An evidence assessment has been carried out by the Clinical Effectiveness Team, NEW Devon CCG. Garth Franklin, Clinical Guidance Manager, joined the meeting for this item.

Patients with chronic kidney disease (CKD) undergoing haemodialysis are at risk of lower serum levels of water soluble vitamins as a result of their treatment, drug interactions and dietary restrictions. Renavit® is a multivitamin tablet containing eight B vitamins and vitamin C and is indicated for the dietary management of water soluble vitamin deficiency in this group of patients. All the vitamins contained in Renavit® were at levels below the lowest concentration at which a toxic or adverse effect had been observed.

Renavit® is a new product in the UK and closely matches European Best Practice Guidelines. Alternative treatments for this group of patients include off-licence use of Ketovite® vitamins or imported products with no UK licence. Ketovite® is included in the Eastern Devon formulary for dialysis to prevent deficiency (unlicensed indication) but contains appropriate levels of only 3 of the 9 vitamins recommended by recent European guidelines.

Specialist groups in the UK and Europe recommend water-soluble vitamin supplementation for dialysis patients although it was noted that benefit has not been assessed in randomised controlled trials. A large observational study carried out across 7 countries suggested that dialysis patients receiving supplements containing water-soluble vitamins have a 16% lower relative risk of mortality (95% CI 6% to 24%) compared to those not receiving vitamins. Routine supplementation of fat soluble vitamins is not recommended in CKD and patients should be discouraged from purchasing standard multivitamin preparations.

Renavit® and Ketovite® both cost £3.50 for 28 days treatment. The average cost of the unlicensed vitamin preparation Dialyvit® is £28 per item. The preferential prescribing of Renavit® is likely to be cost neutral or cost saving.

The committee discussed issues pertinent to this treatment:

- Recent evidence based on current dialysis treatments is not available and unlikely to become available (UK practice has changed since the Dialysis Outcomes and Practice Patterns Study was undertaken). The single observational study is limited evidence and with obvious sources of bias, however European Guidelines suggested that water soluble vitamin supplementation was safe and probably beneficial.
- Patients are receiving medical treatment and are told to restrict their diets which results in deficiency. Most commercially available vitamin supplements contain fat soluble vitamins and are not recommended for this group of patients.
- Current clinical practice includes the routine use of vitamin supplementation with products which do not match European guidelines recommendations as closely as Renavit.

The committee voted 5 to 1 in favour of commissioning Renavit for the dietary management of water soluble vitamin deficiency in renal failure patients receiving dialysis. Members voting for and against commissioning renavit noted a lack of strong supporting evidence for vitamin supplementation.

ACTION: Commissioning policy to be published.

12 Update from NICE Planning, Quality and Assurance Group (NPAG)

The following issues were reported to CPC:

- Dr Alison Round had join NPAG to provide GP representation. Both Dr Alison Round and Dr Mick Braddick will be undertaking some work for NPAG where guidance has a primary care impact.
- A discussion had taken place with regard to the commissioning role of NHS England. NHS England will be contacted regarding shared work.
- Northern and Western localities were not present at the meeting. Both had agreed that locality representation was less important on this group than the assurance that the group has appropriate processes and contained the right skills.
- NICE TA280 recommends abatacept in rheumatoid arthritis, recently a new subcuatenoeus formulation has become available which offers cost and patient convenience benefits – a paper on the use of a subcutaneous preparation of Abatacept will be brought to the CPC meeting in September.

13. Any other business

Change of meeting venues and future meeting dates.

Venues for some of the meetings due to take place over the next few months have changed:

- 10.00 – 12 noon, Wednesday 4th September 2013 – County Hall, Exeter
- 10.00 – 12 noon, Wednesday 9th October 2013 – Tiverton Hospital, Tiverton
- 10.00 – 12 noon, Wednesday 20th November 2013 – The Watermark, Ivybridge

Meetings are being scheduled for 2014. Details to be circulated with the meeting minutes.

ACTION: Details of future meetings to be circulated with the meeting notes

Appeals Procedure

The issue of an appeals procedure was raised. A brief discussion took place with regard to possible routes and arbitration. It was agreed that CR and JR would consider the issues further and report to a future meeting.

ACTION CR and JR to consider appeals process and report back to CPC.

Summary of actions		
	Action	**Lead**
13/20	Options appraisal for declaration of interests to be brought to future meeting.	Rebecca Heayn/Chris Roome
13/21	NHS Devon, NHS Plymouth and Torbay Care Trust policies on circumcision to be reissued as joint NEW Devon CCG and South Devon and Torbay CCG commissioning policy.	Rebecca Heayn
13/22	NHS Devon and NHS Plymouth policies on Planned Treatment Abroad to be removed from NEW Devon CCG website. Website to indicate that funding of planned treatment aboard is the responsibility of NHS England and a link to NHS Choices to be provided.	Rebecca Heayn
13/23	South Devon and Torbay CCG to be informed that their policy planned treatment abroad is no longer valid.	Rebecca Heayn
13/24	Lixisenatide commissioning policy to be published.	Rebecca Heayn
13/25	Flutiform commissioning policy to be published.	Rebecca Heayn
13/26	Renavit commissioning policy to be published.	Rebecca Heayn
13/27	Details of future CPC meetings to be circulated with meeting minutes.	Fiona Dyroff
13/28	Appeals procedure to be considered and report brought to future CPC meeting.	Chris Roome/ Jo Roberts